March 6, 2025

Becton, Dickinson and Company
Katherine Cicala
Senior Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K250344
Trade/Device Name: BD Phoenix™ Automated Microbiology System
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: Class II
Product Code: LON
Dated: February 6, 2025
Received: February 6, 2025

Dear Katherine Cicala:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250344

Device Name
BD Phoenix™ Automated Microbiology System

Indications for Use *(Describe)*
The BD Phoenix Automated Microbiology System is intended for the in vitro rapid identification (ID) and the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram-positive bacteria from pure culture belonging to the genera Staphylococcus, Enterococcus, other gram positive cocci and gram positive bacilli and of most Gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for Enterobacteriaceae and Non-Enterobacteriaceae.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

<*Back to* **page1**>, <**TOC**>

1. Special 510(k) Summary

Summary Preparation Date

03 Feb 2025

I. Background Information:

A. 510(k) Number

K250344

B. Applicant

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152

Establishment Registration Number: 1119779

Contact: Katherine Cicala
Telephone: 908-517-6281

C. Proprietary and Established Names

BD Phoenix™ Automated Microbiology System

D. Regulatory Information

Table 1 – Regulatory Information

Product Name	Product Code(s)	Classification	Regulation Section	Panel
BD Phoenix™ Automated Microbiology System	LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	Microbiology

Common name: Automated microbiology system

II. Intended use/Indications for Use:

A. Indications for Use:

The BD Phoenix Automated Microbiology System is intended for the in vitro rapid identification (ID) and the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most gram-positive bacteria from pure culture belonging to the genera Staphylococcus, Enterococcus, other Gram positive cocci and gram positive bacilli and of most Gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for Enterobacteriaceae and Non-Enterobacteriaceae.

<*Back to* **page1**>, <**TOC**>

B. Intended Use

The BD Phoenix™ Automated Microbiology System is intended for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically significant bacteria. The BD Phoenix™ System provides rapid results for most aerobic and facultative anaerobic Gram-positive bacteria as well as most aerobic and facultative anaerobic Gram-negative bacteria of human origin. The BD Phoenix System is also intended for the rapid identification of yeast and yeast-like organisms.

C. Special Conditions for Use Statements(s):

Rx- For Prescription Use Only

III. Device/System Characteristics:

A. Device Description:

BD Phoenix is an automated system for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically relevant bacterial isolates. The BD Phoenix System utilizes a redox indicator to detect organism growth in the presence of an antimicrobial agent. Measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations. The Phoenix instrument reads and records the results of the antimicrobial tests contained in the panel and interprets the reactions (based on the organism identification) to give a minimal inhibitory concentration (MIC) value and category interpretations (susceptible, intermediate, resistant, or not susceptible).

The BDXpert™ System is a rule-based software tool that provides expert advice based on organism ID and AST results obtained by broth micro-dilution on the BD Phoenix Instruments. BDXpert rule development is based on published information available through standards organizations, current scientific literature, and FDA's STIC; custom rules may be user defined if desired. The BDXpert System rule logic is applied to the susceptible, intermediate, and resistant (SIR) result, which is based on the breakpoint table and interpretation rule set included either in the BDXpert System on the standalone Phoenix instruments or through the BDXpert System on the connected BD EpiCenter™ data management system (EpiCenter) or BD Synapsys™ Informatics Solution (Synapsys). The resulting instrument report contains information such as: MIC interpretation, BDXpert rules, special messaging, resistance markers, etc. The expert results can then be sent to the Laboratory Information System (LIS).

Synapsys is a browser-based software platform operating in the clinical lab setting, offering secure connectivity and data storage, integrated workflows, and analytics tools. Synapsys consists of software servers operating the application and database, securely networked through a facility IT infrastructure to diagnostic instrumentation, external healthcare IT systems such as the LIS, and browser-enabled client devices for operating the system. Synapsys connects BD lab automation and diagnostic instruments to a common database and provides a single user interface to integrate laboratory workflows. Synapsys provides bi-directional communication with BD Phoenix and is able to process ID and AST results received from a BD Phoenix instrument. The system will automatically associate a known organism ID result, regardless of source, to any ID/AST or AST only Phoenix panel(s) that have the same accession/isolate number and lack an organism ID.

B. Principle of Operation:

The BD Phoenix Automated Microbiology System is a broth-based microdilution method that utilizes a redox indicator (colorimetric oxidation-reduction) to enhance the detection of organism growth. The MIC is determined by comparing growth in wells containing serial two-fold dilutions of an antibiotic to the growth in "growth control wells" that contain no antibiotic.

IV. Substantial Equivalence Information:

A. Predicate Device Names(s):

BD Phoenix™ Automated Microbiology System

B. Predicate 510(k) Numbers(s):

K131331

C. Comparison with Predicate(s):

Table 2 – Comparison with the Predicate

Device & Predicate Device(s):	**Device: K250344 BD Phoenix™ Automated Microbiology System (Synapsys connectivity)**	**Predicate: K131331 BD Phoenix™ Automated Microbiology System (EpiCenter connectivity)**
Device Trade Name	BD Phoenix™ Automated Microbiology System	Same
General Device Characteristic Similarities		
Intended Use/Indications for Use	Rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically significant bacteria	Same
Technology	Automated growth-based detection	Same
Methodology	Determination of MIC using serial two-fold dilution format	Same
Read Method	Automated	Same
Inoculation Methods	Manual: BD PhoenixSpec nephelometer Automated: BD Phoenix AP Instrument	Same
Result Reported	Report results as minimal inhibitory concentration (MIC) and categorical interpretation (S, I, R)	Same
Incubation Time	< 16 hours	Same
Algorithms	ID and AST algorithms used to generate results	Same
Custom Rules	User can create custom rules based upon local medical practices	Same
General Device Characteristic Differences		
BDXpert availability	Stand-alone Phoenix instrument, EpiCenter or Synapsys	Stand-alone Phoenix instrument or EpiCenter
BDXpert built-in functionality	Functionality added for Disease Specific Breakpoint Interpretation, Source Specific Breakpoint Interpretation, Zone Breakpoint Interpretation, and Dose Dependent Interpretations	Functionality can be added by the customer through the use of custom rules

V. Performance Characteristics (if/when applicable):

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2016, IEC 62304:2015, ISO 14971:2019 and FDA guidance for the

"Content of Premarket Submissions for Device Software Functions" (issued June 14, 2023). Software verification and validation activities demonstrate that BD Phoenix Instrument connected to Synapsys will perform as intended when used in accordance with device labeling.

VI. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.